

MEDICAL LABORATORY BOARD MINUTES

Date: October 13, 2005

Time: 9:00 a.m., CDT

Location: Cumberland Room
Ground Floor, Cordell Hull Building
425 Fifth Avenue North
Nashville, TN 37247

Members Present: Kelly S. Terry, MT Chairman
Jere Ferguson, MD, Vice-Chairman
Dennis Carter, MD
Edward McDonald, MD
John C. Neff, MD
Thomasa Cooper, Medical Technologist
Norman Crowe, Independent Laboratory Manager/Representative
Yvonne Davis, Medical Technologist
Martha Duncan, Medical Technologist
Alison McDonald-Spakes, Cytotechnologist

Members Absent: Linda Lahr, Medical Technologist
Delores Voigt, MT Hospital Administrator

Staff Present: Lynda S. England, Medical Technologist, Director
Cheryl H. Thacker, Medical Technologist, Consultant
Robbie Bell, Director-Health Related Boards, Ex-Officio Board Member
Robert Kraemer, Jr., Advisory Attorney
Brandi Snow Bozarth, Litigating Attorney
Onezean Otey, Jr., Medical Technologist Consultant/Surveyor,
East Tennessee Regional Office
Sandra S. Bogard, Medical Technologist Consultant/Surveyor,
Middle Tennessee Regional Office
Irmgard Brown, Medical Technologist Consultant/Surveyor,
Middle Tennessee Regional Office
Mary Hamblen, Medical Technologist Consultant/Surveyor
West Tennessee Regional Office
Karon Daniels, Medical Technologist Consultant/ Surveyor,
West Tennessee Regional Office

Medical Laboratory Board
October 13, 2005

Staff Absent:

Julia Daniels, Medical Technologist Consultant/ Surveyor
East Tennessee Regional Office
Jerry Kosten, Rules Manager

Quorum:

A sufficient number of board members were present to constitute a quorum.

Presiding Officer:

The meeting was called to order by the Board Chairman, Kelly S. Terry, beginning at 9:10 a.m.

Ms. Terry introduced the newest appointed member of this board, John C. Neff, M.D. Dr Neff was appointed to serve as the pathologist-educator.

Board Members introduced themselves to the audience.

Welcome:

Ms. Terry welcomed the guests and visitors to the board meeting.

Board Minutes:

A motion to approve the July 13, 2005 Committee minutes was made by Dr. McDonald.

Second: Mr. Crowe

These minutes were approved.

A motion to approve the minutes of the full board from the July 14, 2005 meeting was made by Dr. Ferguson.

Second: Dr. Carter

The minutes were approved.

Board Report-Personnel & Education Committee:

Kelly Terry, MT
Board Chair

Ms. Terry presented a report of the actions of the Personnel & Education Committee meeting held on October 12, 2005.

Motion to accept this report: Dr. McDonald

Second: Dr. Neff

The report was approved.

Minutes
Medical Laboratory Board

October 13, 2005

Contested Cases: Brandi Bozarth
Litigating Attorney

1-Ronald J. Lessard, MT

Memphis, TN 38114

A motion to ratify this letter of reprimand was made by Dr. Ferguson.

Second: Dr. McDonald

Approved.

2-Bobbie J. Westbrooks, MT

Memphis, TN 38114

A motion to ratify this letter of reprimand was made by Dr. McDonald.

Second: Ms. Duncan

Approved.

Board Report-Tennessee Professional Peer Assistance Program:

Mike Harkreader, MA, RN

TNPAP State Director

Mr. Harkreader gave two (2) reports to the board:

1-Quarterly Report, July 1, 2005 until September 20, 2005, stated there were seven (7) referrals with zero (0), one (1) successfully completed the program. All seven (7) referrals were because of a history of arrest that was reported on the initial application for licensure. All referrals were made by the board's administrative office.

2-Annual Report-July 1, 2004 until June 30, 2005, stated there were eight (8) referrals with only one (1) signing a monitoring agreement. Two (2) individuals were in treatment during that period while six (6) refused to participate in the program. The referral sources consisted of three (3) referrals from the board's administrative office, three (3) referrals from the individual's employer and two (2) others from anonymous sources. TNPAP will report to the Bureau of Investigations those individuals that refused to be monitored by this advocacy agency.

Motion to accept this report: Ms. Duncan

Second: Ms. Cooper

Approved.

Minutes

Medical Laboratory Board

October 13, 2005

A copy of Mr. Harkreader's report is on file in the board's administrative office.

Board Report-Rules:

Jerry Kosten-Rules Manager

A. Rules Amendments:

Mr. Kraemer reported on a rulemaking hearing held July 8, 2005 concerning the following amendments to:

1-Rule 1200-6-1-.03 Concerning the Use of Titles.

2-Rule 1200-6-1.13 Concerning Temporary Licenses.

3-Rule 1200-6-1-.19 Concerning Screening Panels.

4-Rule 1200-6-2-.08 Concerning Advertising.

5-Rule 1200-6-3-.20 Concerning Advertising.

There were no comments during the rulemaking hearing to these proposed rule changes.

A motion to adopt these amendments was made by Dr. Ferguson.

Second: Mr. Crowe

A roll call vote was taken with all members present voting aye.

B. Authorize Rulemaking Hearing:

The board authorized a rulemaking hearing to be held December 16, 2005 for:

Amendments to:

1. Rule 1200-6-3-.12 Referral of Cultures to the Department of Health.

a. Shiga-like toxin producing *Escherichia coli* non-0157(STEC).

b. Shiga-like toxin positive stools and/or EIA positive broth shiga-like toxin.

c. Change *Escherichia coli* 0157: H-17 to *Escherichia coli* 0157.

Minutes

Medical Laboratory Board

October 13, 2005

A motion to authorize a rulemaking hearing was made by Dr. Ferguson.

Second: Ms. Duncan
Approved.

2. Rule 1200-6-3-.16(1)(b) 2 Board appearance for addition of analyte to previously granted point of care exemption.

A motion to authorize a rulemaking hearing was made by Dr. Ferguson.

Second: Ms. Duncan
Approved.

Ratifications:

The following items were presented to the Board for ratification per staff, state surveyor or facility request:

- 1) Exemptions for point of care testing procedures (POCT) in a licensed facility (See Attachment 1).
- 2) Initial licenses for Clinical Laboratory Facilities (See Attachment 2).

Board Director's Report/Discussion:

Lynda S. England BS MT(ASCP)
Director

Ms. England reported quarterly administrative office/staff activities to the Board members. This report included administrative office statistics, referrals from this office for TNPAP for peer assistance services and website update information.

Motion: Ms. Duncan
Second: Dr. Ferguson
Report Approved.

The complete director's report is filed in the administrative office.

Direct More Than Three (3) Labs

Rule 1200-6-3-.13(5) Medical Lab Facilities:

There were no requests made to the Board during this meeting.

Minutes
Medical Laboratory Board
October 13, 2005

Reinstatement of License: There were no requests for licenses to be reinstated during this meeting.

Reports/Discussion:

Reports:

Regional Consultant/Surveyor – Proficiency Testing (PT) &
Complaint Investigations/Licensed Laboratory Facilities

East Tennessee Regional Office-Julia Daniels, Consultant II/Surveyor;
Onezean Otey, Jr., Consultant I/Surveyor

Mr. Otey gave the report:

Unsatisfactory/ Unsuccessful Proficiency Testing:

The East Tennessee Regional Office reported three (3) facilities with a first occurrence of unsuccessful participation in proficiency testing events.

Facility #1 Unsuccessful PT Analyte Bacteriology

Facility #2 Unsuccessful PT Analyte Cell ID

Facility #3 Unsuccessful PT Analyte Carbamazepine

All facilities responded with an acceptable plan of correction to include technical assistance and testing personnel competency verifications. No patient results were affected during these events.

Complaint Investigations: The East Tennessee Regional Office conducted zero (0) investigation(s) during the last quarter of 2005.

Middle Tennessee Regional Office- Sandra S. Bogard, Consultant II/Surveyor; Irmgard A. Brown, Consultant I/Surveyor

Ms. Brown gave the report:

Unacceptable/Unsuccessful Proficiency Testing:

The number of licensed laboratories demonstrating a first occurrence of unsuccessful proficiency testing events (two out of three events) was four (4):

Minutes
Medical Laboratory Board
October 13, 2005

Laboratory #1: Unsuccessful PTT and CKMB.

Laboratory #2: Unsuccessful PT for Blood Cell Identification

Laboratory #3: Unsuccessful PT for Blood Cell Identification.

Laboratory #4: Unsuccessful PT for PCO₂.

All facilities responded with an acceptable plan of correction.

Complaint Investigations:

The Middle Tennessee Regional Office has conducted zero (0) complaint investigation(s) during this quarter.

West Tennessee Regional Office-Mary J. Hamblen, Consultant
II/Surveyor; Karen Daniels, Consultant I/Surveyor

Ms. Daniels gave the report:

Unacceptable/Unsuccessful Proficiency Testing:

The number of state licensed laboratories with second occurrence of unsuccessful proficiency testing (three out of four or three in a row):
One (1)

Complaint Investigations:

There were zero (0) complaint investigations from the West Tennessee Regional Office this quarter.

Motion to accept these regional reports: Dr. Neff
Second: Dr. McDonald
Report Approved.

Minutes
Medical Laboratory Board
October 13, 2005

Reports/Discussion:

Health Related Board's Report/Discussion:
Robbie Bell, Director

Ms. Bell did not give a report during the board meeting.

Office of General Counsel Report:
Robert J. Kraemer, Jr.
Advisory Attorney

Mr. Kraemer led the discussion of the following items:

Continuing Education, Temporary Licensure & Lab Test Orders (04-1554)-The rulemaking hearing was held on December 17, 2004 and these amendments were adopted by the Board on January 14, 2005. These amendments were sent to the Attorney General on January 18, 2005 and were signed by the Attorney General and filed with the Secretary of State on August 8, 2005. These rules become effective October 22, 2005.

Criminal Background Checks & Screenings (05-1026)-The rulemaking hearing was held on March 24, 2005 and these amendments were adopted by the Board on April 14, 2005. They were sent to the Attorney General on April 19, 2005 and they are still there.

Director, Delegation, Reportable Cultures and POC (05-1170)-The rulemaking hearing was held on July 8, 2005 and these amendments were adopted by the Board on July 14, 2005.

2005 Legislation Amendments (05-1327)-The rulemaking hearing was held on September 26, 2005 and after response to comments, these amendments are ready for adoption at this meeting.

Minutes
Medical Laboratory Board
October 13, 2005

Litigation:

The Office of General Counsel currently has zero (0) open disciplinary cases pertaining to the Medical Laboratory Board.

Topics for Discussion: None.

Motion to Accept Report: Dr. Neff

Second: Dr. Carter

Report Approved.

Bureau of Investigations (BIV) Report:

Ms. England gave this report from information provided by the Bureau of Investigation which included three (3) open complaints in BIV which were from December 2004. One complaint was added in August, 2005. Currently per Mr. Kraemer's report there are zero (0) complaints in BIV for review.

Motion to Accept Report: Ms. McDonald-Spakes

Second: Ms. Davis

Report Approved.

Office of Health Licensure & Regulation:

Judy Eads, RN

Assistant Commissioner of Health

Ms. Eads gave a report on the progress of HRB's move to Metro Center scheduled for later this year. The preliminary plans have been submitted and hopefully the move will be soon. There will be plenty of parking spaces outside the building. Lodging for board members will be close. The building should be more user friendly for staff, board members and the public in general.

Ms. Terry was presented a plaque by Ms. Eads, in recognition of her service as a board member for the past eight (8) years and especially her efforts as board chair for four (4) of those years.

Minutes

Medical Laboratory Board

October 13, 2005

Financial Report:

Lisa Tittle

Fiscal Officer

A copy of the financial report for the fiscal year 2004-2005 was mailed

to each board member earlier in the month. A copy of this report is included in each member's board book and also on file in the administrative office.

Waived Testing Procedures:

There were no additions or deletions made to the waive test lists.

Point of Care Task Force:

There was no report made by the task force during this meeting.

Review Eligibility of Medical Laboratory Director:

No requests were presented to the Board during this meeting.

Other Business:

- 1-“Factual Situation-#1” The Board discussed the scenario of “Direct Access Testing” and Physician Office Laboratories vs. Referral Laboratories.” The board decided to work with the Board of Medical Examiners and their attorney to establish guidelines/rules and statute changes pertaining to this subject.
- 2- “Factual Situation’#2” The Board discussed the testing of blood donor platelets for bacterial contamination. These procedures are required by the American Association of Blood Banks as of March 2004. It was determined that compliance with these regulations would not necessitate a change in the current rules and regulations.

Medical Laboratory Board
October 13, 2005

- 3-“Factual Situation-#3” The Board discussed the personnel requirement necessary in the utilization of a fully automated pipetting system for pooling of samples for nucleic acid testing. The Board determined licensed individuals must

perform this procedure as this procedure/process was part of a clinical testing event.

Election of Board Chair:

Ms. McDonald-Spakes nominated Ms. Linda Lahr to be the Board Chair for the 2006 calendar year. Ms. Lahr has served as Chairman for the Personnel & Education Committee for several years.

Second: Mr. Crowe

Approved.

Statement of Next Meeting:

The next meeting will be held on January 12, 2006 beginning at 9 am, CST in the Cumberland Room, Ground Floor Cordell Hull Building, 425 Fifth Avenue North, Nashville, TN 37247-1010.

Record of Adjournment:

The meeting adjourned at 11:50 am CDT on a motion properly filed by Ms. Duncan.

Second: Dr. McDonald.

Approved.

Linda Lahr, MT
Chairman, Tennessee Medical Laboratory Board

Date

Page 1
Attachment 1
Medical Lab Board
Point of Care Exemption Requests
October 13, 2005

REQUEST FOR EXEMPTION-POINT OF CARE TESTING PROCEDURES

1. **Cumberland Medical Center**
421 South Main Street

Crossville, TN 38555

Facility Representative: Carolyn W. Smith

This facility request was for:

1- Registered Nurses (RN's) and Certified Registered Nurse Anesthetists (CRNA's) to perform and report arterial blood gases in the Surgical Units utilizing the IL GEM Premier 3000 iQM instrument.

Motion: Dr. McDonald

Second: Dr. Neff

Approved.

2-Registered Nurses (RN's) and Certified Registered Nurse Anesthetists (CRNA's) to perform and report activated clotting times (ACT's) in the Surgery Units utilizing the Actalyke Mini instrument.

Motion: Dr. McDonald

Second: Mr. Crowe

Approved.

2. **LeBonheur Children's Medical Center**
50 North Dunlap
Memphis, TN 38103

Facility Representative: Kathy Connely

This facility request was for Certified Registered Nurse Anesthetists (CRNA's), Perfusionists, Registered Nurses, Registered Respiratory Therapists, Certified Respiratory Therapists and Registered Radiological Technologists to perform and report creatinine analysis utilizing the i-STAT instrument.

Page 2
Attachment 1
Medical Laboratory Board
Point of Care Exemption Requests
October 13, 2005

These tests will be performed in the following areas: the Emergency Department, Pediatric ICU, Cardiac Card ICU, Transitional Care Unit, Neonatal ICU, Surgery Department, ECMO Unit, Pediflite Department, Special Care Unit, Cardiac Catherization Laboratory and throughout the facility.

Motion: Dr. McDonald
Second: Dr. Neff
Approved.

Ms. Davis recused herself from this discussion and vote.

3. **Williamson Medical Center**
2021 Carothers Avenue
Franklin, TN 37067

Facility Representative: Patti Walton, MT(ASCP)
Assistant Laboratory Administrator

This request was for Radiology Technicians to perform and report creatinine testing procedures in the Radiology Department utilizing the i-STAT instrument.

Motion: Dr. McDonald
Second: Mr. Crowe
Approved.

4. **Southern Hills Medical Center**
391 Wallace Road
Nashville, TN 37211

Facility Representative: Teresa Jenkins
Director of Laboratory Services

This facility requested an exemption to allow Phlebotomists to perform and report Ivy Bleeding Times.

Page 3
Attachment 1
Medical Laboratory Board
Point of Care Exemption Requests
October 13, 2005

Note: The Board approved this request although some members expressed concern that Ivy Bleeding Times represent an outdated standard of care available to patients.

Motion: Mr. Crowe
Second: Dr. Neff

Dr. McDonald and Ms. Duncan voted nay.
Approved.

5. **St. Thomas Hospital**
 4220 Harding Place
 Nashville, TN 37202

Facility Representative: Wilma Hausler, MT
QA/Point of Care Specialist

This facility made the following exemption requests:

1-Permit Registered Nurses and Cardiovascular Technicians to perform and report activated clotting times (ACT's) in the Electrophysiology/Non-Invasive Cardiology Laboratory utilizing the i-STAT instrument.

Motion: Dr. Neff
Second: Dr. Ferguson
Approved.

2-Permit Registered Nurses to perform and report INR/PT testing throughout the hospital utilizing the i-STAT instrument.

3-Permit Registered Nurses to perform and report INR/PT in the Coumadin Clinic utilizing i-STAT instrument.

Motion: Dr. Neff
Second: Dr. Ferguson
Approved.

Dr. McDonald and Ms. McDonald-Spakes recused themselves from this discussion and vote.

Page 4
Attachment 1
Medical Laboratory Board
Point of Care Exemption Requests
October 13, 2005

6. **Centennial Medical Center**
 2300 Patterson Street
 Nashville, TN 37203

Facility Representative: Molly Wynn, MT(AMT)

This request was for licensed Nurse Practitioners and licensed Nurse Midwives to perform and report fern testing procedures and wet preps in the Women's OB Triage Unit.

Motion: Dr. Ferguson
Second: Dr. McDonald
Approval.

Ms. Duncan recused herself from the discussion and vote.

Page 1
Attachment 2
Initial Facility Licenses
Medical Laboratory Board
October 13, 2005

INITIAL FACILITY LICENSES: REGIONAL SURVEYOR RECOMMENDATION:

East Tennessee Medical Group Laboratory
266 Joule Street
Alcoa, TN 37701

Medical Laboratory Director: Elizabeth Hubbard, M.D.
Anatomic/Clinical Pathology

Specialties: General Immunology, Hematology, Clinical Chemistry, Urinalysis,
KOH, Wet Prep, Strep A Screen, Occult Blood, H. Pylori, and UCG.

Surveyor: Onezean Otey, Consultant I
East TN Regional Office

Motion: Dr. Ferguson
Second: Dr. Carter
Approved.